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# FDAMA STAKEHOLDER MEETING

**APRIL 28, 1999**

**Talking with Stakeholders About FDA Modernization**

**Your question/comments will become part of Docket Number: 99N-0386

Fax to: 1-888-361-4011 (on April 28 **only**)

✓ **Site: Atlanta, GA**

**Title (required)** ☒ Dr. ☐ Mr. ☐ Mrs. ☐ Ms.

**First Name (required)** Lorne

**Last Name (required)** Garrettson

**Organization** Emory Univ School of Medicine

**Stakeholder Group** ✓ stakeholder group you represent

☐ Consumer ☐ Consumer Group ☒ Health Professional ☐ Industry ☐ Association ☐ Other

**Center** ✓ the center/product area your comments address

☐ Center for Biologics
☐ Center for Devices and Radiological Health
☐ Center for Veterinary Medicine
☐ FDA General
☑ Center for Drug Evaluation and Research
☐ Center for Food Safety and Applied Nutrition
☐ Office of Regulatory Affairs

**Questions to Stakeholders**

Please check the box next to the stakeholder question/s from the March 22, 1999, Federal Register notice which your question/comment addresses.

- ☐ **1.** What actions do you propose the Agency take to expand FDA's capability to incorporate state-of-the-art science into its risk-based decision-making?
- ☐ **2.** What actions do you propose to facilitate the exchange and integration of scientific information to better enable FDA to meet its public health responsibilities throughout a product's life cycle?
- ☐ **3.** What actions do you propose for educating the public about the concept of balancing risks against benefits in public health decision-making?
- ☐ **4.** What actions do you propose to enable FDA and its product centers to focus resources on areas of greatest risk to the public health?
- ☐ **5.** What additional actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation of our modernization efforts?
- ☐ **6.** Additional Comments on FDA Modernization Efforts.

**YOUR COMMENT/QUESTION**

1- What is the time line for implementing the list of approved drugs which require testing in infants and children

2- Drug interactions and adverse effects of drugs continue to be a major problems. What is FDA's role now and are there new initiatives for the future.

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